

Practitioner's Docket No. 701586-052823-US

PATENT

IN THE UNITED STATES RECEIVING OFFICE

International Application Number	International Filing Date	International Earliest Priority Date
PCT/US2003/30701	30 September 2003 (30.09.2003)	30 September 2002 (30.09.2002)

TITLE OF INVENTION: METHODS OF TREATING CANCER USING ADENOSINE AND ITS ANALOGS

APPLICANT(S) FOR EO/DO: The Trustees of Boston University
INVENTOR(S)/APPLICANT(S) FOR US: RAVID, Katya and LU, Jun

CERTIFICATE OF MAILING

I hereby certify that this correspondence, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as Express Mail Label No. EV 653000729 US in an envelope addressed to MAIL STOP PCT, Commissioner of Patents, Box 1450, Alexandria, VA 22313-1450 .

Date: June 21 2005

Debra J. Kellom
Debra J. Kellom

MAIL STOP PCT
Commissioner for Patents
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Alexandria, VA 22313-1450

Sir/Madam:

INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §1.56, 1.97, and 1.98, Applicants wish to bring to the Examiner's attention the following references, References C1-C48, cited in the attached Forms PTO/SB/08a and b.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- X (1) within three (3) months of the Filing Date or before the mailing date of the First Office Action on the merits; or

- (2) within three months of the mailing date of the PCT International Search Report;
or
- (3) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

— A copy of the International Search Report is enclosed herewith.

It is respectfully requested that each of the documents shown on the attached form(s) PTO/SB/08a be made of record in this application.

Copies of these documents (CHECK ONE):

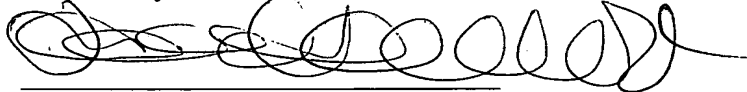
- X are enclosed herewith that have not been previously submitted; or
- have been cited in the parent application, and are thus not being resubmitted herein.

FEE AUTHORIZATION

The Commissioner is authorized to charge fee deficiencies or credit overpayments associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Date: June 21, 2005

Respectfully submitted,



Ronald I. Eisenstein (Reg. No. 30,628)
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21 JUN 2005

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Substitute for form 1449 PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/529,524
				Filing Date	03/29/2005
				First Named Inventor	Katya Ravid
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	6	Attorney Docket Number	701586-052823-US

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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

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		Examiner Name	To be assigned
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		Attorney Docket Number	701586-052823-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	C1	Altucci, L., Addeo, R., Cicatiello, L., Dauvois, S., Parker, M. G., Truss, M., Beato, M., Sica, V., Bresciani, F., and Weisz, A. 17beta-Estradiol induces cyclin D1 gene transcription, p36D1-p34cdk4 complex activation and p105Rb phosphorylation during mitogenic stimulation of G(1)-arrested human breast cancer cells. <i>Oncogene</i> , 12: 2315-2324, 1996.	
	C2	Barbieri, D., Abbracchio, M. P., Salvioli, S., Monti, D., Cossarizza, A., Ceruti, S., Brambilla, R., Cattabeni, F., Jacobson, K. A., and Franceschi, C. Apoptosis by 2-chloro-2'-deoxy-adenosine and 2-chloro-adenosine in human peripheral blood mononuclear cells. <i>Neurochem Int</i> , 32: 493-504, 1998.	
	C3	Brambilla, R., Cattabeni, F., Ceruti, S., Barbieri, D., Franceschi, C., Kim, Y. C., Jacobson, K. A., Klotz, K. N., Lohse, M. J., and Abbracchio, M. P. Activation of the A3 adenosine receptor affects cell cycle progression and cell growth. <i>Naunyn Schmiedebergs Arch Pharmacol</i> , 361: 225-234, 2000.	
	C4	Cariou, S., Donovan, J. C., Flanagan, W. M., Milic, A., Bhattacharya, N., and Slingerland, J. M. Down-regulation of p21WAF1/CIP1 or p27Kip1 abrogates antiestrogen-mediated cell cycle arrest in human breast cancer cells. <i>Proc Natl Acad Sci U S A</i> , 97: 9042-9046, 2000.	
	C5	Cataldo, L. M., Zhang, Y., Lu, J., and Ravid, K. Rat NAP1: cDNA cloning and upregulation by Mpl ligand. <i>Gene</i> , 226: 355-364., 1999.	
	C6	Colquhoun, A. and Newsholme, E. A. Inhibition of human tumour cell proliferation by analogues of adenosine. <i>Cell Biochem Funct</i> , 15: 135-139, 1997.	
	C7	Couse, J. F. and Korach, K. S. Estrogen receptor null mice: what have we learned and where will they lead us? <i>Endocr Rev</i> , 20: 358-417, 1999.	
	C8	Decking, U. K., Schlieper, G., Kroll, K., and Schrader, J. Hypoxia-induced inhibition of adenosine kinase potentiates cardiac adenosine release. <i>Circ Res</i> , 81: 154-164, 1997.	
	C9	Dubik, D. and Shiu, R. P. Mechanism of estrogen activation of c-myc oncogene expression. <i>Oncogene</i> , 7: 1587-1594, 1992.	

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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C10	Dubik, D., Dembinski, T. C., and Shiu, R. P. Stimulation of c-myc oncogene expression associated with estrogen-induced proliferation of human breast cancer cells. Cancer Res, 47: 6517-6521, 1987.	
C11	Ferguson, D. R., Kennedy, I., and Burton, T. J. ATP is released from rabbit urinary bladder epithelial cells by hydrostatic pressure changes—a possible sensory mechanism? J Physiol, 505 (Pt 2): 503-511, 1997.	
C12	Fishman, P., Bar-Yehuda, S., and Vagman, L. Adenosine and other low molecular weight factors released by muscle cells inhibit tumor cell growth. Cancer Res, 58: 3181-3187, 1998.	
C13	Fishman, P., Bar-Yehuda, S., Ohana, G., Pathak, S., Wasserman, L., Barer, F., and Multani, A. S. Adenosine acts as an inhibitor of lymphoma cell growth: a major role for the A3 adenosine receptor. Eur J Cancer, 36: 1452-1458, 2000.	
C14	Fishman P, Bar-Yehuda S, Barer F, Madi L, Multani AS, Pathak S. The A3 adenosine receptor as a new target for cancer therapy and chemoprotection. Exp. Cell Res. 269 (2): 230-6, 2001	
C15	Fishman, P., Bar-Yehuda, S., Madi, L., and Cohn, I. A3 adenosine receptor as a target for cancer therapy. Anticancer Drugs, 13: 437-443, 2002.	
C16	Foster, J. S. and Wimalasena, J. Estrogen regulates activity of cyclin-dependent kinases and retinoblastoma protein phosphorylation in breast cancer cells. Mol Endocrinol, 10: 488-498, 1996.	
C17	Foster, J. S., Henley, D. C., Bukovsky, A., Seth, P., and Wimalasena, J. Multifaceted regulation of cell cycle progression by estrogen: regulation of Cdk inhibitors and Cdc25A independent of cyclin D1-Cdk4 function. Mol Cell Biol, 21: 794-810, 2001.	
C18	Fredholm, B. B., Ijzerman, A. P., Jacobson, K. A., Klotz, K. N., and Linden, J. International Union of Pharmacology. XXV. Nomenclature and classification of adenosine receptors. Pharmacol Rev, 53: 527-552, 2001.	
C19	Gao, Z., Li, B. S., Day, Y. J., and Linden, J. A3 adenosine receptor activation triggers phosphorylation of protein kinase B and protects rat basophilic leukemia 2H3 mast cells from apoptosis. Mol Pharmacol, 59: 76-82, 2001.	

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Sheet 4 of 6	Attorney Docket Number	701586-052823-US	

C20	Gordon, J. L. Extracellular ATP: effects, sources and fate. Biochem J, 233: 309-319, 1986.	
C21	Grierson, J. P. and Meldolesi, J. Shear stress-induced [Ca ²⁺] _i transients and oscillations in mouse fibroblasts are mediated by endogenously released ATP: J Biol Chem, 270: 4451-4456, 1995.	
C22	Hall, J. M., Couse, J. F., and Korach, K. S. The multifaceted mechanisms of estradiol and estrogen receptor signaling. J Biol Chem, 276: 36869-36872, 2001.	
C23	Horwitz, K. B., Koseki, Y., and McGuire, W. L. Estrogen control of progesterone receptor in human breast cancer: role of estradiol and antiestrogen. Endocrinology, 103: 1742-1751, 1978.	
C24	Kim, S. G., Ravi, G., Hoffmann, C., Jung, Y. J., Kim, M., Chen, A., and Jacobson, K. A. p53-Independent induction of Fas and apoptosis in leukemic cells by an adenosine derivative, CI-IB-MECA. Biochem Pharmacol, 63: 871-880, 2002.	
C25	Klinger, M., Freissmuth, M., and Nanoff, C. Adenosine receptors: G protein-mediated signalling and the role of accessory proteins. Cell Signal, 14: 99-108, 2002.	
C26	Koc, Y., Urbano, A. G., Sweeney, E. B., and McCaffrey, R. Induction of apoptosis by cordycepin in ADA-inhibited TdT-positive leukemia cells. Leukemia, 10: 1019-1024, 1996.	
C27	Kohno, Y., Sei, Y., Koshiba, M., Kim, H. O., and Jacobson, K. A. Induction of apoptosis in HL-60 human promyelocytic leukemia cells by adenosine A3 receptor agonists. Biochem Biophys Res Commun, 219: 904-910, 1996.	
C28	Linden, J. Molecular approach to adenosine receptors: receptor-mediated mechanisms of tissue protection. Annu Rev Pharmacol Toxicol, 41: 775-787, 2001.	
C29	Manni, A., Wright, C., and Buck, H. Growth factor involvement in the multihormonal regulation of MCF-7 breast cancer cell growth in soft agar. Breast Cancer Res Treat, 20: 43-52, 1991.	

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Sheet	5	of	6	Attorney Docket Number	701586-052823-US

C30	Neuman, E., Ladha, M. H., Lin, N., Upton, T. M., Miller, S. J., DiRenzo, J., Pestell, R. G., Hinds, P. W., Dowdy, S. F., Brown, M., and Ewen, M. E. Cyclin D1 stimulation of estrogen receptor transcriptional activity independent of cdk4. Mol Cell Biol, 17: 5338-5347, 1997.	
C31	Ohana G, Bar-Yehuda S, Barer F, Fishman P. Differential effect of adenosine on tumor and normal cell growth: focus on the A3 adenosine receptor. J. Cell Physiol. 186(1): 19-23, 2001	
C32	Olah, M. E. and Stiles, G. L. Adenosine receptor subtypes: characterization and therapeutic regulation. Annu Rev Pharmacol Toxicol, 35: 581-606, 1995.	
C33	Park, W. C. and Jordan, V. C. Selective estrogen receptor modulators (SERMS) and their roles in breast cancer prevention. Trends Mol Med, 8: 82-88., 2002.	
C34	Pianetti, S., Guo, S., Kavanagh, K. T., and Sonenshein, G. E. Green tea polyphenol epigallocatechin-3 gallate inhibits Her-2/neu signaling, proliferation, and transformed phenotype of breast cancer cells. Cancer Res, 62: 652-655., 2002.	
C35	Podhajcer, O. L., Resnicoff, M., Bover, L., Medrano, E. E., Slavutsky, I., Larripa, I., and Mordoh, J. Effect of estradiol and tamoxifen on the anchorage-independent growth of the subpopulations derived from MCF-7 breast carcinoma cells: cytogenetic analysis of the stem cell subpopulation. Exp Cell Res, 179: 58-64, 1988.	
C36	Ralevic, V., Milner, P., Kirkpatrick, K. A., and Burnstock, G. Flow-induced release of adenosine 5'-triphosphate from endothelial cells of the rat mesenteric arterial bed. Experientia, 48: 31-34, 1992.	
C37	Robak, T. The role of nucleoside analogues in the treatment of chronic lymphocytic leukemia-lessons learned from prospective randomized trials. Leuk Lymphoma, 43: 537-548, 2002.	
C38	Romieu-Mourez, R., Landesman-Bollag, E., Seldin, D. C., Traish, A. M., Mercurio, F., and Sonenshein, G. E. Roles of IKK kinases and protein kinase CK2 in activation of nuclear factor-kappaB in breast cancer. Cancer Res, 61: 3810-3818., 2001.	
C39	Schrier, S. M., van Tilburg, E. W., van der Meulen, H., Ijzerman, A. P., Mulder, G. J., and Nagelkerke, J. F. Extracellular adenosine-induced apoptosis in mouse neuroblastoma cells: studies on involvement of adenosine receptors and adenosine uptake. Biochem Pharmacol, 61: 417-425, 2001.	

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C40	Sun, S. and Ravid, K. Role of a serine/threonine kinase, Mst1, in megakaryocyte differentiation. J Cell Biochem, 76: 44-60., 1999.
C41	Tamoxifen for early breast cancer: an overview of the randomised trials. Early Breast Cancer Trialists' Collaborative Group. Lancet, 351: 1451-1467., 1998.
C42	Tey, H. B., Khoo, H. E., and Tan, C. H. Adenosine modulates cell growth in human epidermoid carcinoma (A431) cells. Biochem Biophys Res Commun, 187: 1486-1492, 1992.
C43	Tey, H. B., Tan, C. H., and Khoo, H. E. Modulation of DNA synthesis via adenosine receptors in human epidermoid carcinoma (A431) cells. Biofactors, 4: 161-165, 1994.
C44	Vizi, E., Huszar, E., Csoma, Z., Boszormenyi-Nagy, G., Barat, E., Horvath, I., Herjavec, I., and Kollai, M. Plasma adenosine concentration increases during exercise: a possible contributing factor in exercise-induced bronchoconstriction in asthma. J Allergy Clin Immunol, 109: 446-448, 2002.
C45	Wang, Z., Zhang, Y., Lu, J., Sun, S., and Ravid, K. Mpl ligand enhances the transcription of the cyclin D3 gene: a potential role for Sp1 transcription factor. Blood, 93: 4208-4221., 1999.
C46	Watts, C. K., Sweeney, K. J., Warlters, A., Musgrove, E. A., and Sutherland, R. L. Antiestrogen regulation of cell cycle progression and cyclin D1 gene expression in MCF-7 human breast cancer cells. Breast Cancer Res Treat, 31: 95-105, 1994.
C47	Williams, W., Craver, R. D., Correa, H., Velez, M., and Gardner, R. V. Use of 2-chlorodeoxyadenosine to treat infantile myofibromatosis. J Pediatr Hematol Oncol, 24: 59-63, 2002.
C48	Yao, Y., Sei, Y., Abbracchio, M. P., Jiang, J. L., Kim, Y. C., and Jacobson, K. A. Adenosine A3 receptor agonists protect HL-60 and U-937 cells from apoptosis induced by A3 antagonists. Biochem Biophys Res Commun, 232: 317-322, 1997.

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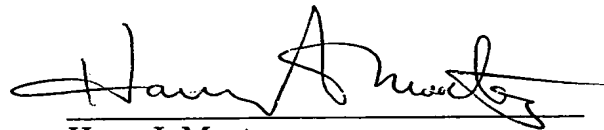
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Harry I. Moatz
Director of Enrollment and Discipline